

Remarks

Claims 1, 2, 4-8, 10, and 12-15 are pending in this application. Claim 3 is withdrawn from consideration as drawn to a non-elected species. Claims 5-7 have been canceled. Claims 1, 2, and 14 are canceled herein. Thus, claims 4, 8, 10, 12, 13, and 16 are under consideration. Claims 4, 8, 10, 12, 13, and 15 are amended herein. Claims 4, 8, 10, and 12 have been amended to change their dependency to claim 15. Claim 15 has been amended to correct grammatical errors and remove reference to a diabetic subject. Claim 13 has been amended to recite "a divalent anti-CD3 diphtheria toxin binding mutant immunotoxin." Support for claim 13 as amended can be found at least in original claims 5-7 and throughout the specification. Claim 15 has also been amended to recite "a divalent anti-CD3 diphtheria toxin binding mutant immunotoxin." Support for the recitation of a binding mutant can be found throughout the specification. No new matter is believed to be entered by these amendments.

Priority Claim

The Examiner has rejected applicants' priority claim to U.S. Serial No. 09/636,251, now U.S. Patent No. 6,103,235 with respect to claims 13 and 15. The Examiner's reasoning with respect to these claims is that "the instant claims are drawn to a method of treating diabetes." Applicants respectfully submit that claim 13 and amended claim 15 do not recite a method of treating diabetes or a diabetic subject. Applicants submit that claims 13 and amended claim 15 are fully supported by the '635 patent. As noted by the Examiner in the Office Action mailed on May 20, 2003, "the reference [the '235 patent] differs from the claimed invention only in that it does not teach the method for the treating of diabetes." Moreover applicants note that support can be found for the recitation in claim 13 for "a method of inhibiting a rejection response of a pancreatic islet transplant" can be found at least on column 8, lines 10-18 of the '635 patent where inhibiting a rejection response is discussed and on column 9, lines 35-54 of the '635 patent where pancreatic islet cells as donor tissue for a transplant are discussed. Support for the recitation of "by inducing immune tolerance in the recipient" in claim 13 can be found at least on column 8, line 22 through column 9, line 3 of the '635 patent. Support for "comprising

administering a divalent anti-CD3 diphtheria toxin binding mutant immunotoxin,” can be found at least on column 8, lines 10-18 and column 5, line 3 of the ‘635 patent, and support for “deoxyspergualin” can be found at least on column 8, lines 48-56 of the ‘635 patent where the use of immunosuppressants in conjunction with the immunotoxin is discussed. The ‘635 patent discusses time periods corresponding to the recitation of “during the peritransplant period,” at least on column 9, lines 15-54. Additionally, the function of “reducing the number of T-cell lymphocytes” in claim 13 can be found at least on column 2, lines 44-49, column 8, lines 10-18, and column 9, lines 55-63 of the ‘635 patent, and “promoting long-term survival of the transplant” can be found at least in example 12 of the ‘635 patent, where the long-term survival of grafts using the claimed methods is discussed. Amended claim 15 finds support in the same places as claim 13. In light of the cited support, Applicants respectfully request reconsideration of Applicants’ priority claim.

Objection to the Specification

The Specification has been objected to under 37 CFR 1.75(d)(1) as allegedly failing to provide antecedent basis for the claimed subject matter. Applicants have amended claim 13 and 15 to recite “binding site mutant.” Applicants believe that as amended, the claims are properly supported and receive antecedent basis in the specification. Applicants believe this objection to be overcome and respectfully request its withdrawal.

35 U.S.C. § 103

Claims 1, 2, 4-8, 10, and 12-15 are rejected under 35 U.S.C. § 103 (a) as allegedly being obvious over U.S. Patent No. 6,103,235 (the ‘235 patent). Applicants note that claims 1, 2, and 14 are canceled herein. Applicants respectfully traverse this rejection. Applicants previously submitted a corrected priority claim to U.S. Serial No. 09/636,251 which is a continuation of and claims priority to U.S. Serial No. 08/439,409, now U.S. Patent No. 6,103,235. The Examiner has denied this claim to priority. Applicants submit that claims 13 and amended claim 15 are supported by the priority documents as noted above. Applicants respectfully request

reconsideration of the priority claim. In light of the support detailed above and favorable reconsideration, the present application claims priority to the '235 patent. Therefore, the present application and the '235 patent have the same priority date and the '235 patent cannot render obvious the present invention. Applicants submit that the present basis for rejection does not have merit, and its withdrawal is respectfully requested.

Claims 1, 2, 4, 8, 10, and 12-15 are rejected under 35 U.S.C. § 103 (a) as allegedly being obvious over WO 96/32137 in view of Henretta et al. (*Transplantation Proceedings* (1994) 26: 1138-1139). Applicants note that claims 1, 2, and 14 are canceled herein. Applicants respectfully traverse this rejection. Applicants have herein shown support for their claim to priority to U.S. Serial No. 08/843,409, now U.S. Patent No. 6,103,235 and requested reconsideration of the claim to priority. Applicants submit if reconsideration is granted that Applicants' have a priority date of at least April 15, 1997. The publication date of WO96/32137 is October 17, 1996, less than one year prior to the April 15, 1997 priority date. The subject matter of the WO96/32137 publication represents the work of the Applicants. Applicants previously submitted a declaration of Dr. Neville under 37 C.F.R. 1.132 establishing the WO96/32137 represents the Applicants' own work. Thus the WO96/32137 publication is not prior art and cannot render obvious the present invention. In light of the declaration and applicants request for reconsideration of the priority claim, applicants believe this rejection has been overcome and respectfully request withdrawal of the rejection, as the remaining cited references fails to teach each element of the claimed invention

U.S.C. § 112, first paragraph

Claim 13 is rejected under 35 U.S.C. § 112, ¶ 1, for allegedly lacking enablement. In particular, the Examiner has rejected claim 13 for allegedly not being enabling for "a method for the treatment of diabetes comprising administration of an immunotoxin, an immunosuppressant, and pancreatic islet cells from a donor." Applicants have amended claim 13 to recite "a divalent anti-CD3 diphtheria toxin binding mutant immunotoxin." Support for this amendment is noted above. Applicants note that this amendment in no way limits the scope of the claim as the scope

of “immunotoxin” was clear as previously written. Applicants believe this rejection has been overcome and respectfully request the rejection be withdrawn.

Claim 14 is rejected under 35 U.S.C. § 112, ¶ 1, for allegedly lacking written description. In particular, the Examiner has rejected claim 14 for allegedly not providing written description for “an anti-CD3-diphtheria toxin immunotoxin.” The Examiner concedes that support is present for “divalent” or “monovalent” anti-CD3-diphtheria toxin immunotoxins. Applicants note that this rejection is now moot due to the cancellation of claim 14. Applicants respectfully request the rejection be withdrawn.

Claim 15 is rejected under 35 U.S.C. § 112, ¶ 2, for allegedly being indefinite. In particular, the Examiner has rejected claim 15 for grammatical errors. Applicants have amended claim 15 to remove grammatical errors. Applicants believe no new matter has been added by this amendment as the claim was clear as previously written. Applicants respectfully request the rejection be withdrawn.

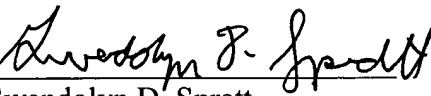
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Pursuant to the above amendments and remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issue.

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of \$120.00, representing the one (1) month extension of time fee for a large entity under 37 C.F.R. § 1.17(a)(3) and a Request For Extension of Time are enclosed. This amount is believed to be correct. However, should additional fees be required, the Commissioner is hereby authorized to charge any additional amount or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.


Gwendolyn D. Spratt
Reg. No. 36,016

NEEDLE & ROSENBERG, P.C.
Customer No. 23859

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

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Gwendolyn D. Spratt

8-1-05
Date